HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
M356dn

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

March 16, 2000

WARNING LETTER

Ref: 2000-DAL-WL-05

VIA FEDERAL EXPRESS

Mr. James L. Porter
President/Treasurer
Shield Technology, Inc.
7024 South Indianapolis
Tulsa, Oklahoma 74136

Dear Mr. Porter:

This letter concerns the over-the-counter (OTC) marketing and promotion of "**chimal**™ TECHNOLOGY SKIN SHIELD," and "StarLee Skin **SHIELD**" by your firm. During an inspection of your facility on October 25, 1999, and January 6, 2000, our investigator obtained immediate container labels and promotional labeling for these products. Promotional labeling includes flyers, booklets, and a collection of information and data assembled under the title "Chimal/Starlee Skin Shield," which is distributed in whole or in part to purchasers of these products.

Based on their respective labels and labeling, these products are intended to form an impervious "barrier" or "shield" on the skin. They are labeled and promoted for long term effectiveness equivalent to that provided by protective gloves in preventing adverse effects and diseases caused by contact with (a) various harmful or caustic substances (e.g., chemicals, solvents, acids, alkaline compounds, and fiberglass), (b) substances that cause allergic reactions (e.g., poison ivy, poison oak, poison sumac, and latex), (c) biological materials (e.g., blood and urine), and (d) pathogenic microorganisms (e.g., fungi, enterohemorrhagic *Escherichia coli*, hepatitis B virus, human immunodeficiency virus, and other bloodborne pathogens). These products are also represented as effective in preventing viral diseases [e.g., acquired immune deficiency syndrome (AIDS), hepatitis, and verruca vulgaris], fungal diseases (e.g., dermatophytosis), and in treating diaper rash, decubitus ulcers, minor cuts, and burns. Thus, "**chimal**™ TECHNOLOGY SKIN SHIELD" and "StarLee Skin **SHIELD**" are "drugs" as defined by Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

The intended uses described above are conveyed through these products' trade names and through statements, claims, and representations made on immediate container labels and promotional labeling, which include:

> ". . . SKIN SHIELD . . . The ultimate in skin protection with Nonoxynol 9 . . . protects your skin with a unique formula that creates protection against harmful or caustic substances . . . For maximum protection apply Skin Shield every four hours . . . will not wash off . . . has reduced the contact dermatitis . . . Protection against Poison Ivy, Poison Oak, & Poison Sumac . . . Prevents the absorption of blood born [sic] pathogens & allergic reactions . . . Protection against . . . dangerous chemicals . . . Skin Shield Layer . . . repels water soluble ions and molecules that can cause irritation to skin . . . Protection from paints and fiberglass . . . forms an effective barrier to the penetration of strong acids . . . Except for concentrated solutions of sulfuric Acid and Hydrofluoric Acid, all of the other chemicals would be repelled . . . Acetone . . . Nitric Acid . . . Toluene . . . an antimicrobial product against enterohemorrhagic Escherichia coli . . . the product offers protection from chemical burns associated with sulfuric or hydrochloric acids . . . can be used as secondary hand protection under rubber or plastic gloves . . . acts as a barrier on skin and can be used to protect workers from bacteria, chemical and acid burns and dermatitis . . . contains nonoxynol 9 . . . effective in preventing the transmission of viruses through the skin . . . could significantly reduce the incidence of . . . dermatophytosis, a fungal disease known as ringworm, and 'verruca vulgaris,' a viral wart . . . this product proved . . . that rubber gloves are a thing of the past . . . to protect . . . from harmful infectious diseases and organisms . . . found to help latex sensitive people . . . started the decubitus wound to heal . . . for . . . diaper rash . . . to . . . minimize or eliminate occupational exposure to Hepatitis B virus (HBV), human immunodeficiency virus (HIV) and other bloodborne pathogens . . . does not permit blood or other potentially infectious materials to pass through or reach the employee's . . . skin . . . or other mucous membranes . . ."

From a review of the information and the respective product formulations and labeling obtained during our inspection, we have determined that "**chimal**™ TECHNOLOGY SKIN SHIELD" and "StarLee Skin **SHIELD**" do not qualify for evaluation under the ongoing OTC Drug Review being conducted by the Food and Drug Administration (FDA). Representations for prophylactic "barrier" uses, such as those noted above, are not described in any of the rulemakings being considered under the Review. We are also not aware of any substantial scientific evidence that these drug products, as formulated and labeled, are generally recognized among scientific experts as safe and effective for these labeled uses. Thus, "**chimal**™ TECHNOLOGY SKIN SHIELD" and "StarLee Skin **SHIELD**" are "new drugs" as defined by section 201(p) of the Act and neither may be legally marketed in the United States without an approved new drug application (NDA) under section 505(a) of the Act.

In addition, since the adequacy of the labeled directions for these "barrier" uses has not been established, these products are misbranded under section 502(f)(1) of the Act. They are also misbranded under section 502(o) of the Act because they are not listed with FDA as required by section 510 of the Act.

The violations described above are not meant to be all-inclusive. It is your responsibility to ensure that all drug products manufactured and distributed by your firm comply with the Act. Federal agencies are advised of the issuance of all Warning Letters pertaining to drugs and devices so that they may take this information into account when considering the award of contracts. Additionally, your contract manufacturers and sub-distributors of the "**chimal**™ TECHNOLOGY SKIN SHIELD" and "StarLee Skin **SHIELD**" products will be advised of the issuance of this letter.

It is important to note that Mr. William Dixon, co-owner of your firm, has already been advised of the violative nature of products like those named above. On January 7, 1994, Mr. Dixon received a Warning Letter from FDA's Denver District for "StarLee Skin **SHIELD**," which was labeled and marketed at that time for skin "barrier" and disease prevention and treatment uses that are very similar to representations being made for the currently marketed product. We request that you take action immediately to correct these violations. Failure to do so may result in regulatory action without further notice and may include seizure and/or injunction.

Please respond to this office in writing within fifteen (15) working days of receipt of this letter. Your response should describe the specific actions you will take, or have taken, to correct the violations described above. It should also include an explanation of each step being taken to prevent recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed.

Your reply should be directed to Reynaldo R. Rodriguez, Jr., Compliance Officer, at the above letterhead address.

Sincerely,

Michael A. Chappell
District Director